

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Linhart et al.

Appl. No: To Be Assigned

Filed: Herewith

For: **Allergy Vaccines Containing Hybrid
Polypeptides**

Art Unit: To Be Assigned

Examiner: To Be Assigned

Atty. Docket: 0273-0006

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination of the above-identified application, Applicants herewith respectfully request the following amendments:

In the Claims:

Please cancel claims 8, 10-12 and 16-19 without prejudice to or disclaimer of the subject matter therein.

Please amend the following claims:

1. (once amended) A hybrid polypeptide comprising at least two different allergenic proteins or fragments thereof, wherein each fragment consists of at least eight consecutive amino acids of the respective allergenic protein.

2. (once amended) A hybrid polypeptide according to claim 1, wherein the hybrid polypeptide comprises at least one complete allergenic protein.

3. (once amended) A hybrid polypeptide according to claim 2, wherein the hybrid polypeptide comprises at least two complete allergenic proteins.

4. (once amended) A hybrid polypeptide according to claim 1, wherein the hybrid polypeptide comprises at least one fragment of an allergenic protein which fragment has a substantially reduced allergenic activity compared with the allergenic protein from which it is derived.

5. (once amended) A hybrid polypeptide according to claim 4, wherein the hybrid polypeptide comprises fragments of at least two different allergenic proteins all of which fragments have a substantially reduced allergenic activity compared with the respective allergenic proteins from which they are derived.

6. (once amended) A hybrid polypeptide according to claim 1, comprising at least three different allergenic proteins or fragments thereof.

7. (once amended) A polynucleotide encoding the hybrid polypeptide of claim 1.

9. (once amended) A cell transfected or transformed with the polynucleotide of claim 7.

13. (once amended) A method for preparing a hybrid polypeptide according to claim 1, comprising:

- a) providing a polynucleotide encoding the hybrid polypeptide;
- b) introducing said polynucleotide into a host cell;

- c) culturing the host cell obtained in b) under conditions such that the hybrid polypeptide is expressed; and
- d) recovering the expressed hybrid polypeptide from the cultured host cell.

14. (once amended) A method according to claim 13, wherein the polynucleotide encoding the hybrid polypeptide is obtained using PCR technology.

15. (once amended) A method for preparing a hybrid polypeptide according to claim 1, wherein the hybrid polypeptide is prepared by chemical synthesis.

Please add the following new claims:

20. (new) A pharmaceutical composition comprising the hybrid polypeptide of claim 1, the polynucleotide of claim 7 or the cell of claim 9.

21. (new) A pharmaceutical composition according to claim 20, further comprising an adjuvant.

22. (new) A method for treating an allergic disorder comprising administering the pharmaceutical composition of claim 20 to a patient in need thereof.

23. (new) A method for inducing tolerance to a given allergen, comprising administering the pharmaceutical composition of claim 20 to a patient in need thereof.

24. (new) A method for providing immunity to a given allergen, comprising administering the pharmaceutical composition of claim 20 to a patient in need thereof.

25. (new) A method for detecting antibodies against a given allergenic protein in a sample, comprising conducting *in vitro* antibody tests employing the hybrid

polypeptide of any one of claims 1 to 6 or conducting *in vitro* or *in vivo* cellular-based tests employing the hybrid polypeptide of any one of claims 1 to 6.

REMARKS

Claims 1-7, 9, 13-15 and 20-25 are pending in the current application. Claims 1-7, 9 and 13-15 have been amended to conform to domestic practice. Claims 8, 10-12 and 16-19 have been canceled. Claims 20-25 have been added to conform canceled claims 8, 10-12 and 16-19 to domestic practice. Support for the amendments to claims 1-7, 9 and 13-15 and for new claims 20-25 is found in, *inter alia*, original claims 1-19. This amendment is believed to introduce no new matter, and thus, its entry is respectfully requested.

Applicants believe that the present application is in condition for examination. If for any reason, the Examiner believes that personal communication will expedite prosecution of this application, then the Examiner is invited to contact the undersigned at the phone number provided.

Respectfully submitted,

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By: 

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Marked-Up Version of the Amended Claims

1. (once amended) A hybrid polypeptide comprising at least two different allergenic proteins or fragments thereof, wherein each fragment consists of at least eight consecutive amino acids of the respective allergenic protein.

2. (once amended) A hybrid polypeptide according to claim 1, wherein the hybrid polypeptide comprises at least one complete allergenic protein.

3. (once amended) A hybrid polypeptide according to claim 2, wherein the hybrid polypeptide comprises at least two complete allergenic proteins.

4. (once amended) A hybrid polypeptide according to claim 1, wherein the hybrid polypeptide comprises at least one fragment of an allergenic protein which fragment has a substantially reduced allergenic activity compared with the allergenic protein from which it is derived.

5. (once amended) A hybrid polypeptide according to claim 4, wherein the hybrid polypeptide comprises fragments of at least two different allergenic proteins all of which fragments have a substantially reduced allergenic activity compared with the respective allergenic proteins from which they are derived.

6. (once amended) A hybrid polypeptide according to [any of claims 1-5 characterized in that it comprises] claim 1, comprising at least three different allergenic proteins or fragments thereof.

7. (once amended) A polynucleotide encoding [a] the hybrid polypeptide [according to any] of [claims 1-6] claim 1.

9. (once amended) A cell transfected or transformed with [a] the polynucleotide [comprising a polynucleotide according to] of claim 7.

13. (once amended) A method for [the preparation of] preparing a hybrid polypeptide according to [any of claims 1-6] claim 1, comprising [the following steps]:

- a) providing a polynucleotide encoding the hybrid polypeptide;
- b) introducing said polynucleotide into a host cell; [and]
- c) culturing the host cell obtained in [step] b) under conditions such that the hybrid polypeptide is expressed; and
- d) recovering the [expression product] expressed hybrid polypeptide from the cultured host cell.

14. (once amended) A method according to claim 13, wherein the polynucleotide encoding the hybrid polypeptide is [prepared] obtained using PCR technology.

15. (once amended) A method for [the preparation of] preparing a hybrid polypeptide according to [any of claims 1-6 characterized in that] claim 1, wherein the hybrid polypeptide is prepared by chemical synthesis.